REMARKS

The present invention relates to a blood coagulation reagent kit capable of detecting lupus-anticoagulant and blood.

In the Office Action of March 29, 2006, claims 1 - 20 were rejected, and claims 2, 5, 8, 9, 10, 12, and 13 were objected to. The objections were based the units of concentration, including a Greek letter separate from the metric unit that it modifies, and omission of an "l" in claim 2.

Regarding the prior art, claims 1, 4, 6 - 14, 19, and 20 were rejected under 35 U.S.C. §102(b) based on U.S. Patent 5,314,695 (Brown) in light of Webster's Dictionary. Claim 1 - 6 and 8 - 13 were rejected under 35 U.S.C. § 102(b) based on Smirnov et al in light of Webster's Dictionary. Furthermore, claims 1, 4, and 6 - 20 were rejected under 35 U.S.C. § 103(a) based on Brown and Webster's Dictionary in light of U.S. Patent 6,395,501 (Rosen). Lastly, claims 1, 7, 16, 18, and 19 were provisionally rejected on the ground of non-statutory obviousness with respect to claims 1, 6, 7, 8, and 9 of co-pending Application No. 11/050,766.

In response to the Office Action, first, claims 2, 5, 8, 9, 10, 12, and 13 have been amended to overcome the objection based on the position of the Greek letter and to correctly indicate the "ml" units.

In addition to the amendments noted above of the foregoing claims, Applicant has herein further amended claims 1, 8, and 14, and new claims 21 - 23 have been added. It is respectfully submitted that for the reasons described below, the pending claims 1 - 23 are patentable over the cited art of record, and are now in appropriate condition for allowance.

The differences between the new claim 21 and the amended claim 8 are the lower limit of the concentration of the phosphatidylserine in the first reagent and upper limit of the concentration of the phosphatidylserine in the third reagent. The lower limit "30 μg/ml" and the upper limit "20μg/ml" are recited in the current claims 9 and 10 respectively.

The new claim 22 is a method claim corresponding to current reagent kit claim 1. The new claim 23 is a method claim based on the amended reagent kit claim 8.

Features of the present invention (Okuda)

A reagent kit of the present invention is a reagent kit for detecting lupus anticoagulant.

The reagent kit is a combination of two kinds of reagents which show different coagulation time from each other in the presence of lupus anticoagulant (hereinafter, simply called as "LA") due to the difference in the content of phosphatidylserine to the total content of phospholipids, i.e. PS content ratio (see the last paragraph of page 9 and the paragraph bridging

pages 10 - 11 in the specification). In other words, in the case that a blood sample from an LA positive patient is measured with use of the first and second coagulation time reagents, a first coagulation time with the first coagulation time reagent is different from a second coagulation time with the second coagulation time reagent.

Particularly, the reagent kit of the present invention has an advantage of discriminating LA-positive patients from individuals having other anticoagulant diseases. In the case of blood samples from LA positive patients measured with use of the inventive reagent kit, these samples may show noticeable difference between the first coagulation time and the second coagulation time. On the other hand, in the case of a blood sample from the patients having a blood coagulation factor deficiency or a blood sample from patients administered with warfarin or heparin, these blood samples show similar coagulation times with use of any of the first or the second coagulation time reagents. Please see from page 11, line 19 to page 13, line 17, and TABLE 2 of the specification.

With respect to the reagent kit of the amended claim 8, the combination of the first and second reagents corresponds to the first coagulation time reagent in claim 1, and the combination of the third and fourth reagents corresponds to the second coagulation time reagent in claim 1.

§102 Rejections based on Brown and Smirnov

Brown's invention relates to a prothrombin time reagent using recombinant human tissue factor as disclosed at lines 16 to 18 of column 1. Although the Office Action makes reference to "testing APTT coagulation times" in the final two lines at the bottom of page 3 in the Office Action, this is incorrect.

Brown discloses a coagulation time reagent containing phospholipids including phosphatidylserine. Furthermore, Brown discloses prothrombin times measured with use of reagents having various ratio of PS content to the total content of phospholipids in Table 1 thereof.

The disclosure of Smirnov relates to phospholipids vesicle having various concentrations of PS for determining the optional concentration of PL for prothrombin activation and factor Va inactivation.

However, Brown and Smirnov are silent as to measuring coagulation time of blood containing LA. Thus Brown does not teach or suggest that a combination of two reagents having different PS content ratios from each other may show absence of LA. Therefore, neither Brown nor Smirnov disclose a reagent kit for detecting LA.

Accordingly, the inventive reagent kits of amended claims 1 to 21 are not anticipated by Brown or Smirnov. Furthermore, method claims 22 and 23 are not obvious therefrom.

§ 103 Rejection based on Brown and Webster's Dictionary in light of Rosen

The Office Action asserted that claims 1, 4, and 6 - 20 are not patentable over Brown in light of Rosen, because Rosen discloses phospholipids in combination with certain activators, and it would have been obvious to a person of ordinary skill in the art to substitute the activator disclosed in Rosen for tissue factor in the phospholipid composition taught by Brown to derive the present invention.

Applicant respectfully disagrees with the view set forth in the Office Action. Even if Rosen is combined with Brown, the present inventive reagent and method would not be obvious to a person of ordinary skill in the art, because Brown fails to disclose a reagent kit for detecting LA as described above, to say nothing of Rosen.

Accordingly, it is respectfully submitted that the rejections under 35 U.S.C. § 103, based on Brown (and Webster's Dictionary) in light of Rosen should be withdrawn.

The Double Patenting Rejection

The reagent kit of U.S. Application 11/050,766 (hereinafter simply referred to as the '766 application") is a reagent kit for detecting LA. However, the present inventive reagent kit is different from the reagent kit of '766 application for the following reason.

The present inventive reagent kit comprises a combination of reagents having different PS content ratio from each other. On the other hand, the reagent kit of the '766 application comprises a combination of reagents having different phosphatidylethanolamine (PE) content ratio from each other as recited in claim 1.

It appears that the Examiner may not have correctly understood a feature of '766 application. Particularly, the Examiner said that

> "Claim 1 of '766 is drawn to a kit having first and second reagents wherein the concentration of PS in the first reagent is 40 to 280 μM ...." (at lines 7 - 8 on page 7 of Office Action).

However, it is clear that claim 1 of the '766 application recites the PE concentration of the first and second coagulation time reagents, not PS concentration thereof, in the wherein clause.

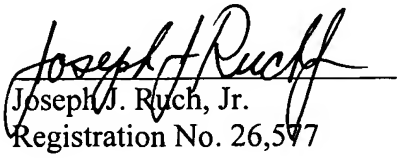
Accordingly, the inventive reagent kit is different from the reagent kit of '766 application, and it is respectfully submitted that the double patenting rejection should be withdrawn.

In view of the above, reconsideration and allowance of pending claims 1 - 23 of this application are now believed to be in order, and such actions are hereby earnestly solicited.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C. telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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